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IN THE

Supreme Court of the United States

OCTOBER TERM, 1956

V. E. IRONS, INC., AND V. E. IRONS, *Petitioners,*

v.

UNITED STATES OF AMERICA, *Respondent.*

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

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Petitioners pray that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the First Circuit, entered in the above-entitled case on April 24, 1957.

CITATIONS TO OPINION BELOW

The District Court did not render an opinion. The opinion of the Court of Appeals, printed in Appendix A, *infra,* p. 1a, has not yet been published.

JURISDICTION

The judgment of the Court of Appeals was entered on April 24, 1957 (R. 1049). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether the construction by the Court of Appeals of Section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act, (21 U.S.C. 352 (f)(1)), under which the "labeling" of a drug product must contain directions for use for conditions specified in oral lectures and advertising, not constituting labeling under Section 201(m) of the Act (21 U.S.C. 321(m), renders Section 502 (f)(1) invalid as a matter of constitutional law because of the resultant vagueness and indefiniteness.

2. Whether this construction of Section 502(f)(1) by the Court of Appeals is correct.

3. Whether, where a criminal information charges a defendant with having "caused" the introduction or delivery for introduction into interstate commerce of a misbranded drug product, the Government must charge and prove wilfulness pursuant to 18 U.S.C. 2(b), as amended.

4. Whether material error was committed by the district court, constituting a miscarriage of justice, in refusing to permit expert opinion testimony on behalf of petitioners relating to the issue of whether the representations alleged to have been made by petitioners had in fact been made.

STATUTES INVOLVED

The statutory provisions involved are Sections 201 (m), 301(a), 502(a) and 502(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(m), 331(a), 352(a), 352(f)(1)), and 18 U.S.C. 2(b), as amended. They are printed in Appendix B, *infra*, p. 23a.

STATEMENT

Petitioners distribute in interstate commerce various natural vitamin products. In the marketing of their products, petitioners lay great stress upon the fact that they are selling only natural vitamins, as distinguished from high potency synthetic vitamins. There is a crusading school of thought in this country, although it appears to be a minority view, which is of the firm opinion that natural foods, including natural vitamins, are of far greater value in aiding good health than foods and vitamins produced synthetically. The Government prosecuted the petitioners by an information containing six counts. In each of Counts II to VI, the Government charged that the petitioners had falsely represented their products as a cure or treatment for various diseases in violation of Section 502(a) of the Act (21 U.S.C. 352 (a)), and that the labeling of petitioners' products had not borne adequate directions for use under Section 502(f)(1) (21 U.S.C. 352(f)(1)). The Government offered proof, which was admitted in evidence, that conditions had been adverted to in oral lectures and advertising, and that the labeling did not contain directions for use for these conditions. Count I charged that the label of petitioners' products had not contained information required by Section 403(j) of the Act (21 U.S.C. 343(j)), and the regulations issued thereunder. After

trial, the jury found the petitioners guilty on all counts.[1] The District Court sentenced petitioner V. E. Irons to serve one year in jail on each of the six counts of the information, to run concurrently, and sentenced petitioner V. E. Irons, Inc., to pay a fine of $1,000 on each count.

REASONS FOR GRANTING THE WRIT

Petitioners submit that the construction of Section 502(f)(1) of the Act by the Court of Appeals raises an important constitutional question as to whether the Section, as so construed, is rendered invalid for vagueness and indefiniteness. Petitioners further urge that the Court of Appeals has incorrectly decided an important question of Federal law, the construction of Section 502(f)(1), and that the constitutional question and question of statutory construction have not been, and should be, settled by this Court. There have been numerous criminal prosecutions under the Federal Food, Drug, and Cosmetic Act similar to that under which the petitioners were convicted, and many more condemnation actions bottomed on the same legal theory. Settlement of these questions, involving both liberty and property, is, therefore, in the public interest. A further important question, not yet decided by this Court, is whether 18 U.S.C. 2(b), as amended, is applicable to prosecutions alleging violations of the Federal Food, Drug, and Cosmetic Act and other laws where "causing" is charged in the information or indictment. This presents a question of substantial importance in the enforcement of criminal law.

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[1] It is not known whether the verdict on Counts II to VI was based on the charge under Section 502(a), the charge under Section 502(f), or both.

There is a conflict in the lower courts as to whether expert opinion testimony is admissible on the issue of whether representations alleged to have been made by a defendant had in fact been made. This is of particular significance since the courts have permitted the Government to introduce such testimony in prosecutions but have refused to permit defendants to introduce such testimony in defense.

1. These major issues, which had been raised below by petitioners, were not met by the Court of Appeals. Petitioners contended that if Section 502(f)(1) were so construed as to require that the labeling of a drug product must contain directions for use for conditions referred to in oral lectures or advertising, not constituting "labeling", the Section was rendered void for vagueness and indefiniteness. The only discussion of this point in the twenty page opinion of the Court of Appeals is the statement, infra, pp. 18a, 19a, that "it is a bit late in the day to sustain the assertion that the Federal Food, Drug, and Cosmetic Act is unconstitutionally vague." Petitioners also urged below that inasmuch as the Government had chosen to charge that petitioners had "caused" the Commission of the offenses complained of, the failure, in each of the six counts of the information, to charge and prove wilfulness, was fatally defective in view of the provisions of 18 U.S.C. 2(b), as amended. The Court of Appeals apparently adverted, *infra*, p. 18a, to this point by stating that "Appellants present a variety of other defenses, some of which are clearly untenable".

2. The construction of Section 502(f)(1) by the Court of Appeals renders the Section void for vagueness and indefiniteness. A statute which forbids the doing of an act in terms so vague that men of com-

mon intelligence must necessarily guess at its meaning, and differ as to its application, violates the first essential of due process of law. *Connally* v. *General Construction Co.*, 269 U.S. 385. Even if the Section were construed so as to require directions for use only for the conditions specified in the "labeling" of the product, the Section would still have distinct elements of ambiguity. What are "adequate directions for use?" How full must directions be to meet the test of adequacy? Adequate directions in what respects, in what conditions, and for whom? How can the ordinary person possibly know what "adequate directions for use" contemplate? But the Government's construction of the Section, requiring, in an Act devoted to "labeling", that labeling bear adequate directions for use for conditions mentioned in oral lectures delivered perhaps thousands of miles away from the shipment of the product or the location of the distributor, magnifies the ambiguity so as to render the Section impossible for the ordinary person to grasp by a reading of its language.

As this Court said in *Cardiff* v. *United States*, 344 U.S. 174, holding invalid for indefiniteness Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374):

> The vice of vagueness in criminal statutes is the treachery they conceal either in determining what persons are included or what acts are prohibited. Words which are vague and fluid (Cf. United States v. L. Cohen Grocery Co., 225 U.S. 81, 65 L. ed. 516, 41 S. Ct. 298, 14 ALR 1045) may be as much of a trap for the innocent as the ancient laws of Caligula.

Applicability of the principle for which that case stands has been shadowed by some doubt cast by cases holding constitutionally valid certain statutes prohibiting or requiring, in language which seems somewhat vague, certain conduct. See, e.g., *United States* v. *Petrillo,* 332 U.S. 1. Petitioners submit that the rationale lies in whether the statute in question ties the prohibited act to a specific intent or purpose to achieve an indicated result. Apparently somewhat indefinite language may be upheld if the statute in question makes intent to achieve a proscribed purpose an element of the crime. See *Hygrade Provision Co.* v. *Sherman,* 266 U.S. 497; *Gorin* v. *United States,* 312 U.S. 19; *F. & A. Ice Cream Co.* v. *Ardens Farm Co.,* 98 F. Supp. 180 (S. D. Calif.). If this is correct, Section 502(f)(1) is clearly within the class of statutes that offend due process. For not only is wilfulness not an element of the crime under the Federal Food, Drug, and Cosmetic Act, but the penalties of the law may be imposed upon one wholly innocent of knowledge or intent to achieve a purpose proscribed by the statute. *United States* v. *Dotterweich,* 320 U.S. 277.

3. The construction of Section 502(f)(1) by the Court of Appeals which, we submit, accentuates the constitutional infirmity, was not only not required but was incorrect. It took five years. (1933-1938) to pass the Federal Food, Drug, and Cosmetic Act. It is clear, from a study of the legislative history, that every important and controversial problem and proposal, as well as a myriad of unimportant problems and proposals, was discussed and thrashed out in the greatest detail. Yet, not a word appears indicating that the Congress intended Section 502(f)(1) to apply to conditions referred to in oral statements or advertising not constituting labeling.

The Government refers to Senate Report No. 361, S. 5, 74th Cong., and Senate Report No. 493, S. 2800, 73d Cong., as disclosing the intent of Congress that labeling must contain directions for use for conditions adverted to in oral lectures and advertising. But the portions of these reports upon which the Government relies were not referring to the section of these bills providing that labeling must contain adequate directions for use, but to entirely different sections defining the various terms used in the bills. And these reports contain no reference whatever to the effect that the provisions with respect to directions for use apply to oral lectures and advertising as well as labeling. Further, these reports accompanied early bills which contained provisions vesting jurisdiction of advertising as well as labeling in the Food and Drug Administration. Thus, as was to be expected, the committees lumped the two together. But when Congress ultimately determined, in the amended Federal Trade Commission Act, to vest jurisdiction of advertising in the Federal Trade Commission, the bills which were then introduced and which culminated in the enactment of the Federal Food, Drug, and Cosmetic Act, and the applicable reports, contained not one reference to any design of Congress to give to the Food and Drug Administration, by indirection, the very jurisdiction over advertising which had already been vested in the Federal Trade Commission. The Federal Food, Drug, and Cosmetic Act, as finally enacted, defined "labeling" but not "advertisement". The amended Federal Trade Commission Act defined "false advertisement" but not labeling. (See 15 U.S.C. 41, 55 et seq.)

Congress knew the difference between the ordinary concepts of labeling and advertising. See Section

301(1) (21 U.S.C. 331(1)), prohibiting "the using, on the labeling of any drug or in any advertising relating to such drug, of any representation or suggestion" that a new-drug application has been approved by the Food and Drug Administration.

Another indication that Congress was and is quite aware of the distinction between advertising and labeling is found in the Oleomargarine Act, 64 Stat. 20. In that statute, Congress referred specifically to labels and sales, and amended the Federal Food, Drug, and Cosmetic Act in such connection, and further referred to advertisements and amended the Federal Trade Commission Act to cover the advertising of margarine.

Of particular interest is the factory inspection amendment to the Federal Food, Drug, and Cosmetic Act (67 Stat. 476, Sec. 704 of the Act, 21 U.S.C. 374, as amended). That amendment provides that "The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished" in connection with a factory inspection shall be a criminal offense. Again, it will be seen that when Congress wished to direct its attention to advertising, as well as labeling, it made its intention entirely clear.

4. The failure to charge or prove wilfulness in the information was fatally defective. Each of the six counts charged the petitioners with "causing" a misbranded product to be introduced and delivered for introduction into interstate commerce. The criminal provisions of the Federal Food, Drug, and Cosmetic Act must be read together with Section 2 of Title 18, which qualifies all Federal criminal statutes. For example, under this Section one would be punished as a principal for aiding or abetting in the commission

of an act prohibited by another statute, including the Federal Food, Drug, and Cosmetic Act, even though that statute is silent as to aiders or abettors. Section 301(a) of the Federal Food, Drug, and Cosmetic Act, read together with 18 U.S.C. 2(b), makes the *causing* of the introduction and delivery for introduction into interstate commerce of a violative product a crime only if the causing was wilful. The first four sections of Title 18, including Section 2, are directed at any violation of Federal law, not merely those contained in Title 18. Many subsequent sections of that Title (see, for example, Sections 5, 6, 7, 9, 11, 12) refer to "this title", but the first four sections are not so limited. 18 U.S.C. 2(b) was enacted subsequent to the passage of the Federal Food, Drug, and Cosmetic Act in 1938, and in 1951 the requirement of wilfulness was added to 18 U.S.C. 2(b). In connection with criminal statutes, which must be strictly construed, it is submitted that it cannot be assumed that Congress chose to circumscribe 18 U.S.C. 2(b) by taking from within its coverage offenses under the Federal Food, Drug, and Cosmetic Act, even though the latter statute also directs itself to "causing."

This is particularly true since the construction which we urge does not limit in any way the substance of the latter statute. This Court held, in *United States* v. *Dotterweich*, 320 U.S. 277, that it is not necessary to allege or prove guilty knowledge or intent in prosecutions instituted under the Federal Food, Drug, and Cosmetic Act. The petitioners could have been charged, as were the defendants in the *Dotterweich* case, with having introduced or delivered for introduction into interstate commerce violative products. In

that event, the Government would not have had the burden of proving intent, let alone wilfulness. But here the Government chose to charge the petitioners with having "caused" the introduction and delivery for introduction into interstate commerce of the violative products and, therefore, took it upon itself to assume the burden, under 18 U.S.C. 2(b), of charging and proving wilfulness.[2]

5. Material error was committed in the refusal to permit expert opinion testimony on behalf of petitioners with respect to the issue of whether petitioners made the representations as charged in the information.

The information alleges that petitioners made various representations to the public to the effect that their product is effective in the cure and treatment of various specific diseases such as cancer, arthritis, heart trouble, diabetes, asthma, etc., and that the product was represented for special dietary uses. These charged representations constitute the foundation for the criminal acts set forth in all of the six counts.

The petitioners attempted to negate these allegations by the proffer of expert opinion testimony. The district court committed material error in refusing to permit such offers of proof. Reference is specifically made to the examination of Dr. N. Philip Norman (R.

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[2] The Court of Appeals also did not advert to the fact that one who causes is an aider and abettor, and that it is essential to the conviction of one so charged that there be proof that there was another person who did the prohibited act. This was not established at the trial. See *Morgan* v. *United States*, 159 F. 2d 85, 87 (C.A. 10); *Malatkofski* v. *United States*, 179 F. 2d 905, 916 (C.A. 1); *United States* v. *Horton*, 180 F. 2d 427, 430-431 (C.A. 7).

455-457).[3] In refusing such testimony, the Court stated that the question was a factual matter for the jury, and therefore, not proper. The district court was correct in stating that the ultimate issue was an issue of fact for the jury. However, that did not make the offer of proof objectionable. Although the jury must make the final determination of fact, proper evidence is admissible, and, in fact, invaluable, to enable the jury to reach its decision.

The necessity of such evidence in aid to the jury is magnified in this case, where we are dealing with charged representations created by taking words out of context from the petitioners' labeling material and by the creation of alleged representations in the form of English words other than the language of the label-

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[3] (R. 455, 456)

Q. And from your reading of the literature in the government's exhibit, do you have an opinion as to whether or not the defendants are claiming cures for specific diseases?

Mr. Lewald: I pray your Honor's judgment to that question.

The Court: Excluded.

Mr. Foley: May I argue the point?

The Court: No. It is for the jury.

(R. 457)

Mr. Foley: And that was, "Considering the literature as a whole, what is your opinion as to the fair import and meaning of the literature".

The Court: It is practically the same question.

Mr. Foley: Well, I think it reads a little differently. One is whether it takes—there are a lot of other things besides cures that have been alleged by the government.

The Court: It is a companion question.

Mr. Foley: Oh, yes, I agree to that.

The Court: And for the same reasons expressed, it is a factual matter for the jury, one of the allegations in the information that the government is to prove.

ing itself. The Government's allegations of alleged representations go beyond the express language of petitioners' labeling.

The type of evidence which petitioners attempted to introduce to defend themselves against the criminal charges is the same kind of evidence heretofore used by the Government, including the Food and Drug Administration, where such evidence served its purpose. *United States* v. *38 Dozen Bottles, More or Less, Labelled in Part Tryptacin,* 114 F. Supp. 461 (1953); *Charles of the Ritz Distributors Corporation* v. *Federal Trade Commission,* 143 F. 2d 676 (C.C.A. 2); *Federal Trade Commission* v. *National Health Aids, Inc. et al.,* 108 F. Supp. 340 (D. Md.); *Benton Announcements, Inc.* v. *Federal Trade Commission,* 130 F. 2d 254 (C.C.A. 2).

In the instant case, the Government did not introduce any evidence in support of its charged representations as it had done in the above-cited cases. When petitioners attempted to employ such evidence, by way of defense, the Government objected and the Court sustained said objection.

In *United States* v. *38 Dozen Bottles, More or Less, Labelled in Part Tryptacin,* 114 F. Supp. 461 (D. Minn.), the Government used the same kind of testimony to prove a similar charged representation of alleged "cure" and in *Stanley Laboratories, Inc.* v. *Federal Trade Commission,* 138 F. 2d 388 (C.A. 9), the Government used the testimony of physicians both as to their own opinion and their opinion of the effect of the advertisement upon the consumer to prove the meaning of advertising material. In both instances, the Court upheld the right of the Government to employ such expert opinion testimony.

The Court of Appeals in the instant case failed to answer this submission of error and further failed to discuss or distinguish the above-cited cases with respect to their applicability to the instant case. It is respectfully submitted that material and prejudicial error was committed by the refusal to permit petitioners to defend themselves against the charges set forth in the information.

Until this Court rules on this issue, we will be left with two different rules of law with respect to the same question. This conflict has created an injustice in that the division among the courts upholds such evidence when employed by the Government and denies it when employed by defendants.

CONCLUSION

For the foregoing reasons, this petition for a writ of certiorari should be granted.

Respectfully submitted,

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May 24, 1957.